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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/890,552	08/02/01	YOKOYAMA	H 0020-4883P

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EXAMINER
JAGOE, D

ART UNIT	PAPER NUMBER
1614	<i>6</i>

DATE MAILED: 10/30/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/890,552	YOKOYAMA ET AL.
	Examiner	Art Unit
	Donna A. Jagoe	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-16 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1.) Certified copies of the priority documents have been received.
 2.) Certified copies of the priority documents have been received in Application No. ____.
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a.) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) Interview Summary (PTO-413) Paper No(s) ____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

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DETAILED ACTION

Claims 1-16 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for l-menthol, does not reasonably provide enablement for l-methanol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. If this is a typographical error, amending the claim to recite l-menthol would obviate the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 provide for the use of l-menthol and an essential oil, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9 and 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 4-8 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high molecular weight compound" in claims 4, 7 and 14 is a relative term which renders the claim indefinite. The term "high molecular weight compound" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "high" the molecular weight can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "high" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The remaining claims are indefinite to the extent that they read on the rejected base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 3-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. U.S. Pat. No. 4,205,685.

The claims are drawn to compositions and methods of use of comprising l-menthol and an essential oil such as peppermint oil in an ointment or patch along with a base of a hydrophilic high molecular weight compound such as gelatin and a polyhydric alcohol such as sorbitol.

Yoshida et al. teach a wet pack (patch) composition comprising gelatin and sorbitol and further comprising menthol and peppermint oil (column 4, line 57 bridging to column 5, line 10). Methods of use such as for headache are recited in column 11, lines 50-66. Regarding the shape of the patch, the composition of Yoshida et al. is pressure molded sheets of 8x12 cm (rectangular) (see examples 2-4, columns 13-14).

2. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. U.S. Pat. No. 5,519,046 A.

Noda et al. teach a patch composition comprising high-molecular weight substances in a proportion of most preferably 5-20% (column 2, lines 36-66) combined with humectants (polyhydric alcohols) in a proportion of from 3% to 60% (column 3, lines 8-27) and water in a proportion of from 20% to 70% (column 3, lines 28-32). L-

menthol and peppermint oil and other essential oils are incorporated in a proportion of from 0.01% to about 10% (column 3, lines 33-50 and column 4, lines 31-38).

3. Claims 1-8 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al. U.S. Pat. No. 6,090,403 A.

Block et al. teach a patch and an ointment comprising about 5% menthol a polymeric gum such as karaya or polyacrylamide from about 5% to about 50% and a polyhydric alcohol such as glycerin or propylene glycol in about 10% to about 60% (column 7, line 50 to column 8, line 7). Patches can measure from about 2 inches by 3 inches to about 4 inches by 5 inches (rectangular shape) for application to *inter alia* the chin, nasolabial area beneath nose (face) and neck (nape of neck). Oil of peppermint along with the menthol is recited in claims 2, 9 and 16. Although the compositions of Block et al. are for congestion instead of migraine headache, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the compositions of the patent are capable of performing the intended use of soothing a migraine headache, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barr et al. U.S. Pat. No. 6,197,823 B1.

The claims are drawn to patch and ointment compositions and methods of use of comprising l-menthol and an essential oil such as lavender oil along with a base of a hydrophilic high-molecular weight compound such as gelatin and a polyhydric alcohol such as sorbitol.

Barr et al. teach topical compositions (column 7, lines 5-17) comprising menthyl lauryl pidolate of which menthol is the active component and acts as an analgesic in an amount of from 0.1% to 16% menthol in the formulation (column 5, lines 16-19). Additional components can be added such as lavender flower oil or lavender oil (column 5, lines 65-66). Other components such as propylene glycol (polyhydric alcohol), xanthan gum (high-molecular weight compound) and water are added (see examples). Methods of use include relief of arthritis pain, neuropathy, post surgical scarring and hemorrhoidal pain. It differs in that it does not teach explicitly the treatment of migraine

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headaches. It would have been obvious to have treated a migraine headache with the compositions of Barr et al. since they are taught to be useful for treatment of pain resulting from *inter alia* arthritis. One of skill in the art would have been motivated to administer the compositions of Barr et al. to treat a migraine headache because they are well known to treat pain.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 308-7921 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

dj

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October 25, 2001

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600

Fred Krass